

Executive Summary Supplement for Requestors of the NDI Causes of Death Variables

If you intend to request the NDI Causes of Death Variables, you are required to address each section below on this form.

If Requesting the Cause of Death:

<p>1. State that you are requesting the cause of death codes and detail how they will be used/ analyzed as part of the study.</p>	
<p>2. State whether you will be conducting death record follow back activities and if so, whether you already have received IRB approval for the death record follow back methodology—involving contacts with next-of-kin, physicians or hospitals. Attach a letter from IRB that indicates they have reviewed and approved your follow back methodology. The letter must include language similar to the following statement (but tailored specifically to the study which was reviewed): “We have reviewed this study in conjunction with your application to use the NDI. We are satisfied that the procedure to be used to obtain additional information on deceased study subjects (from next-of-kin, physicians, hospitals and/or others) provide appropriate protection to the respondents with respect to minimizing respondent burden, maintaining confidentiality, protecting their privacy, and avoiding or minimizing any emotional or other harm that may affect the respondent. Our review included an assessment of all existing and/or proposed contact letters, telephone techniques, questionnaires and consent forms used in the death record follow-back investigations. These were all deemed to be satisfactory.”</p>	
<p>3. State whether or not death certificates will be requested. CMS does not have the death certificates. This would require purchasing the death certificates directly from the States.</p>	
<p>4. State whether you are maintaining a “registry” and if so, whether the cause of death information would be included in the registry once it was obtained from CMS. Indicate when the registry was formed, the eligibility criteria for subjects to be included in the registry and the registry’s objectives.</p>	
<p>5. State whether the cause of death information will be re-released to other parties. CMS will only approve use of cause of death codes under this application and use by the organizations approved on the associated DUA. Any other uses or “rereleases” have to be reviewed and approved by the CMS Privacy Board and the NDI Advisory Panel.</p>	
<p>6. State that the cause of death information received from CMS would not be used for legal or administrative purposes.</p>	

PRA Disclosure Statement: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-XXXX. The time required to complete this information collection is estimated to average [Insert Time (hours or minutes)] per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. **Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact 1-800-MEDICARE.**